REMARKS/ARGUMENTS

Claims 43-83 are presently pending in this application. Claims 1-42 have been canceled.

By way of background, this application is a continuation in part of Application No. 09/378,181, which has issued as U.S. patent 6,450,942.

The new set of claims submitted herewith was favorably considered during the international preliminary examination of the international application. Further, the new set of claims closely resembles the claims in the issued '942 patent but differs from them primarily in that the claims of this application extend the window during which the treatment can be successfully applied. It has been found that the same window is not applicable to everyone, but that treatment within the broader window defined by the new claims is effective.

Thus, independent apparatus claim 43 recites that the "stimulation signals [are] triggered in a time window lying within a range of 5% of the R-R path length before the end of the T-wave and 45% of the R-R path length after the end of the T-wave", whereas, in the claims of the '942 patent, the time window is defined as "lying in the range between -5% and +10% of a respectively associated Q-T systole duration of said electrocardiogram ...."

As a result, independent claims 43, 66 and 78, and the claims depending from them, are allowable for essentially the same reasons why the corresponding claims were allowed in the '942 patent.

In view of the entirely new claims submitted herewith, some of the reasoning for rejecting original, now-canceled claims 1-42 clearly do not apply to the new claims.

Nevertheless, applicants point out that new independent claims 43, 66, 78 and 83 are neither anticipated by nor obvious in view of Krikorian (4,541,417).

Krikorian does not disclose the features of claims 43 and 78 or the existence or possibility of achieving the newly found phenomena of cardioresonance. Indeed applicants could find no suggestion in Krikorian of a reduction in heart rate (=pulse rate). The opposite

appears to be the case; column 9, lines 44 and 45 of Krikorian suggest that high rates are encountered, which is a potential problem.

The bottom curve in Fig. 3 of the present application shows particularly clearly the effect achieved by the present invention. It is nothing short of amazing that applicants have discovered that by applying stimulating electrical pulses with the appropriate timing and duration a new phenomena (discovered by the applicants), and which the applicants call "cardioresonance", sets in which lowers the heart rate and the systolic pressure and thus the load on the heart. Moreover, the blood supply to the heart muscle is improved and a variety of other benefits are attained, such as improved body fat burning and improved muscle tone.

Surprisingly, only minor stimulation is required to achieve this result (which is an indication that a resonance phenomena is present), and the timing of the stimulating pulses and their duration has little or nothing to do with the time blood takes to flow from the point of stimulation to the heart.

Krikorian contains various hypotheses as to how the system described there works, such as bio-chemical processes, column 2, lines 60-68, back pressure during diastole, column 3, lines 1-5, reduced back pressure during systole, column 3, lines 5-8, and providing pumping assistance to the heart, by relaxation of the blood vessel volume when the tetanizing pulse ceases.

Krikorian, however, provides no support for or description of these mechanisms and, based on extensive clinical and experimental tests carried out by or on behalf of applicants, it appears that the explanations given in Krikorian are not correct.

Be that as it may, Krikorian refers to experiments on dogs, see for example column 3, lines 36-41 and in particular column 9, lines 57-64. The latter passage is the only one that quotes specific values for the actual timing and duration of the stimulation used. The values quoted are stimulation occurring 200 milliseconds from the beginning of diastole and having a duration of 50 milliseconds. Since the heart rate of a laboratory dog is typically more than twice that of a human being, this means that the stimulation is applied later than the latest time

specified in independent claims 43, 66 and 78, i.e. significantly later than 45 % after the end of the T-wave, and that the duration of the applied stimulation is outside of the range of 10 to 25% of the T-Q diastole duration.

Thus the values specifically quoted in Krikorian are in ineffective ranges, and they will not achieve the cardioresonance attained with the present invention and which leads to the highly surprising performance curves illustrated in Fig. 3 of the present application. Krikorian contains no corresponding disclosure. Krikorian appears not to have discovered, and Krikorian neither discloses nor in any manner suggests, the highly surprising phenomena of cardioresonance disclosed in the present application and confirmed by the experimental work which has been carried out.

Although Fig. 3 of Krikorian might at first appear to show a situation comparable to the top curve in Fig. 3 of the present application, there is no scale of values in Fig. 3 of Krikorian. Further, it is in any event impermissible to deduce values from schematic drawings. Moreover, if Fig. 3 of Krikorian were viewed as disclosing any values, then it teaches stimulating pulses with durations that are well outside the claimed range.

For these reasons, applicants submit that new independent claims 43, 66 and 78 as well as claim 83 are both novel and not obvious over Krikorian.

In this context, applicants point out that they had extensive contacts with cardiologists and surgeons in the course of their investigations. None have ever even heard of similar work before, which is indicative that Krikorian cannot achieve the results achieved by the present invention. Many of the cardiologists who have learned of the present invention were initially highly skeptical; however applicants' experimental results, which have frequently been obtained with the active participation of the cardiologists concerned, have since convinced them otherwise. Moreover, applicants have presented papers concerning the present invention at the four major international conferences over the last year, which is itself an extraordinary achievement, and which demonstrates the importance given the present invention by experts in the field.

Further, a patient (the father of co-inventor Lapanashvili) had suffered three severe heart attacks, and the sort of videos, called angiography, cardiologists normally make of the hearts of persons having suffered heart attacks were prepared. The patient was subsequently treated with the present invention for over one year while he went about his normal life. After one year the patient saw a specialist cardiologist in Switzerland and asked that he be checked, and the same angiography videos were again taken. The Swiss cardiologist gave the patient a clean bill of health and said he observed no evidence of heart disease. The patient then showed the Swiss cardiologist the angiography videos that had been taken a year earlier, and the Swiss cardiologist would not believe the angiography videos were from the same person.

In another instance, a man working for a large Swiss conglomerate company had chronic heart failure problems. The man was taking large doses of diverse medications, had no energy and was essentially unable to go to work for more than 25% of his time. Through treatment in accordance with the present invention, the man's condition improved dramatically so that he now needs little medication, is able to work again 100% of his time, and his physical performance has improved dramatically.

The inventors have been trying to understand why their invention really works. Although they are still not certain, they believe that what the invention actually does is to stimulate the autonomous nervous system in such a way that the human body is triggered into a variety of self-healing routines.

This further demonstrates why the present invention is not obvious. In the absence of a clear teaching of the mechanisms at work, there is no reason why a person skilled in the art would arrive at the present invention and, except for the present inventors, none did.

CONCLUSION

In view of the foregoing, applicants submit that all pending claims 43-83 are in condition for allowance, and formal notification to that effect at an early date is requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

J. Georg Seka
Reg. No. 24,491

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
JGS:jhw
60258185 v1